Evaluation of a temporary pump in patients with decompensated heart failure

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26259

Bron
NTR

Verkorte titel
IABP-HF

Aandoening

Cardiogenic shock, heart failure

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Delta SvO2 (T3h minus baseline T0h (=mean of two baseline measurements with interval 15 minutes)).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: In severe heart failure, the heart¡¯s pumping power is weak, leading to fluid retention and hospital admission of the affected patient. This project will investigate if a temporary pump (intra-aortic balloon pump, IABP) in the aorta will treat fluid overload so that patients are bridged faster towards recovery or to surgical assist device implantation.

Objective: Evaluation of the benefit of IABP counterpulsation in patients with diuretic-resistant congestive heart failure.
Secondary objectives:

• To lower the burden of disease/improve symptoms, to shorten duration of stay in the hospital, to improve the function of other organs than the heart, and to bridge patients faster to final treatment (medical vs. LVAD vs. transplantation vs. palliative care).

• To create evidence based knowledge and gain better understanding of the disease, resulting in tailor-made treatment.
Study design: Open-label randomized controlled parallel, partial cross-over, study in patients with diuretic-resistant congestive heart failure.

Study population: Patients with congestive heart failure, refractory to treatment with high dosages of intravenous diuretics.

Intervention (if applicable): Patients will be randomized to IABP (without inotrope, group I) or inotrope (without IABP, group II).
Main study parameters/endpoints: Delta SvO2 at T=3h.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients in evident heart failure refractory to high-dose diuretic therapy have a poor prognosis. Escalation therapy will be given by either inotropic therapy (carrying the risks of arrhythmias) or an IABP (carrying the risks of access site and remote complications, <1%). Both treatment options have been successfully applied to save patients.

Doel van het onderzoek

In severe heart failure, the heart¡¯s pumping power is weak, leading to fluid retention and hospital admission of the affected patient. This project will investigate if a temporary pump (intra-aortic balloon pump, IABP) in the aorta will treat fluid overload so that patients are bridged faster towards recovery or to surgical assist device implantation.

Onderzoeksopzet

T=0h, T=3h, T=12h, T=24h, T=48h, T=72h.
At T=48h, a crossover will be performed in clinical non-responders as defined by protocol.

Onderzoeksproduct en/of interventie

Intra-aortic balloon pump vs inotropic therapy

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

CONGESTIVE HEART FAILURE (FIRST EPISODE (¡°DE NOVO¡±) OR WORSENING OF CHRONIC HEART FAILURE) WITH THE FOLLOWING CHARACTERISTICS:

BLOOD PRESSURE Systolic <100 mm Hg

PHYSICAL EXAMINATION Fluid retention (elevated central venous pressure, palpable liver, edema)

ECHO At least moderate tricuspid regurgitation and/or mitral valve regurgitation. Dilated inferior caval vein.

INVASIVE MEASUREMENTS PCWP >15 mmHg; CVP >12 mmHg; SvO2 <55%

NT-PROBNP >200 pg/mL

FLUID BALANCE Neutral or positive despite fluid restriction (1.5L/24h) and administration of high dosages of intravenous diuretics*

TOGETHER WITH: Dysfunction of at least 1 other organ#
PCWP, pulmonary capillary wedge pressure; CVP, central venous pressure.

* Bolus dosage (equal to) 80 mg intravenous furosemide followed by total intravenous dosage equal to total daily loop diuretic dose in furosemide equivalents and (if necessary) doubled, for at least 12h.

Lung: extra oxygen supplementation, kidney: creatinine clearance <50 mL/min, liver enzymes ¡Ý2x upper limit of normal, or lactate levels ¡Ý2.0 mmol/L.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Significant aortic valve regurgitation.

- Absent common femoral artery pulsation.

- Acute myocardial infarction <7 days before inclusion.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2017
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-10-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5979
NTR-old	NTR6143
Ander register	: MEC-2016-475

Resultaten